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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,405	01/24/2002	Laurence J. Zwiebel	N7841 DWS	2561
7590	12/13/2004		EXAMINER	
Douglas W. Schelling, Ph.D. Waddey & Patterson Bank of America Plaza 414 Union Street, Suite 2020 Nashville, TN 37219			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/056,405	ZWIEBEL, LAURENCE J.
	Examiner	Art Unit
	Jon M Lockard	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to a method of identifying an agent that binds to mosquito olfaction molecules, classified in class 436, subclass 501, for example.
 - II. Claims 7-12, drawn to a method of identifying a compound that inhibits binding of a mosquito Arrestin to a mosquito odorant receptor, classified in class 435, subclass 7.93.
 - III. Claims 13-17, 22-26, 31-35, 40-44, 49-53, 58-62, 67-71, 76-80, drawn to polynucleotides of SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, and SEQ ID NO:19, classified in class 536, subclass 23.1.
 - IV. Claim 18-21, drawn to polypeptides of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, and SEQ ID NO:20, classified in class 530, subclass 350.
 - V. Claim 20, drawn to a method of modulating Arrestin 1 biological activity, classification dependent upon compound structure
2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions III and IV are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

4. The polynucleotide of **Group III** and the polypeptide of **Group IV** are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of **Groups III and IV** together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of **Groups III and IV** have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. Furthermore, a search of the nucleic acid molecules of **Group III** would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of **Group IV**. As such, it would be burdensome to search the inventions of **Groups III and IV**.

5. Invention IV and each of I, II, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention IV can be used in the methods of identifying compounds that bind to it, in the methods of modulating its activity, or to make antibodies, which are all materially different methods.

6. Although there are no provisions under the section for “Relationship of Inventions” in MPEP § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentable distinct inventions for the following reasons: Inventions I, II, and V are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, and are not required one for the other.

Further Restriction Within Group I

7. If Group I is elected, further restriction within the elected group is required, as follows: one of the following species of olfaction molecules: SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, or SEQ ID NO:20.

8. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicants are advised that this is not a species election.

Further Restriction Within Group III

9. If Group III is elected, further restriction within the elected group is required, as follows: one of the following species of olfaction molecule nucleic acids: SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:5, SEQ ID NO:7, SEQ ID NO:13, SEQ ID NO:15, SEQ ID NO:17, or SEQ ID NO:19.
10. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicants are advised that this is not a species election.

Further Restriction Within Group IV

11. If Group IV is elected, further restriction within the elected group is required, as follows: one of the following species of olfaction molecule proteins: SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, or SEQ ID NO:20.
12. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicants are advised that this is not a species election.

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13. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

14. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

15. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to

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retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

16. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
December 8, 2004

Brenda Brumback
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